UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND
POLLUTION PREVENTION

18/MAY/2010

MEMORANDUM

Subject:	Name of Pesticide Product:	Tundra Max
	EPA Reg. No. /File Symbol:	1381-EUG
	DP Barcode:	D370218
	Decision No.:	416476
	Action Code:	R320
	PC Codes:	059101 (chlorpyrifos), 128825 (bifenthrin)

From: Eugenia McAndrew, Biologist
Technical Review Branch
Registration Division (7505P)

To: BeWanda Alexander, RM Team 13
Insecticide Branch
Registration Division (7505P)

Applicant: Winfield Solutions, LLC
LLC, P.O. Box 64589
St. Paul, MN 55164-0589

FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
Chlorpyrifos	28.6
Bifenthrin	9.0
Inert Ingredient(s):	62.4
Total:	100.0%

ACTION REQUESTED: The Risk Manager requests: "Please review the attached acute toxicity data submitted to support a new end use premix formulation containing chlorpyrifos and bifenthrin."

BACKGROUND: Winfield Solutions, LLC has submitted a six pack of acute toxicity studies to support the registration of the proposed product, Tundra Max, EPA File Symbol 1381-EUG. The studies were conducted at Stillmeadow, Inc., Sugar Land, Texas with assigned MRID numbers 477921-03 to -08.

RECOMMENDATIONS: The six studies are classified as acceptable.

The acute toxicity profile for Tundra Max, EPA Reg. No. 1381-EUG, is as follows:

Acute oral toxicity	II	Acceptable	MRID 47792103
Acute dermal toxicity	IV	Acceptable	MRID 47792104
Acute inhalation toxicity	IV	Acceptable	MRID 47792105
Primary eye irritation	II	Acceptable	MRID 47792106
Primary skin irritation	IV	Acceptable	MRID 47792107
Dermal sensitization	Negative	Acceptable	MRID 47792108

The basic CSF dated August 7, 2009 should be reviewed and accepted by the TRB Product Chemistry Team.

LABELING: Based on the toxicity profile above, the following are the precautionary and first aid statements for this product as obtained from the Label Review System:

PRODUCT ID #: 001381-00243

PRODUCT NAME: Tundra Max

PRECAUTIONARY STATEMENTS

SIGNAL WORD: WARNING

SPANISH SIGNAL WORD: AVISO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.
(If you do not understand the label, find someone to explain it to you in detail.)

Hazards to Humans and Domestic Animals:

Contains Petroleum Distillate.

May be fatal if swallowed. Causes substantial but temporary eye injury. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Do not get in eyes or on clothing. Wear protective eyewear (goggles, face shield, or safety glasses). Remove and wash contaminated clothing before reuse. Wear: Long-sleeved shirt and long pants, Socks, Shoes, and chemical-resistant gloves (such as Barrier Laminate, Butyl Rubber, Nitrile Rubber, Viton, Barrier Laminate, Viton, Selection Category F, G). If the Selection Category F, G gloves do not provide adequate protection

for this product, the registrant should indicate a specific glove category from the EPA chemical resistance glove selection chart that will provide adequate protection.

First Aid:

If swallowed:
-Call a poison control center or doctor immediately for treatment advice.
-Do not induce vomiting unless told to by a poison control center or doctor.
-Do not give any liquid to the person.
-Do not give anything by mouth to an unconscious person.

If in eyes:
-Hold eye open and rinse slowly and gently with water for 15-20 minutes.
-Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
-Call a poison control center or doctor for treatment advice.

NOTE TO PHYSICIAN: May pose an aspiration pneumonia hazard. Contains petroleum distillate.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

Reviewer: Eugenia McAndrew **Date:** May 18, 2010
Risk Manager (EPA): 13

STUDY TYPE: Acute Oral Toxicity – Rat; OCSPP 870.1100; OECD 425

TEST MATERIAL: Tundra Max (Lot No. V.276.54.3; 28.78% chlorpyrifos and 9.22% bifenthrin; density 1.0239 g/mL; clear red solution)

CITATION: Kuhn, J. (2009) Tundra Max – Acute Oral Toxicity Study (UDP) in Rats. Study Number 12633-08. Stillmeadow, Inc., 12852 Park One Drive, Sugar Land, TX 77478. May 1, 2009. MRID 47792103.

SPONSOR: Winfield Solutions, LLC, P.O. Box 64589, St. Paul, MN 55164-0589

EXECUTIVE SUMMARY: In an acute oral toxicity study (MRID 47792103), seven fasted, young adult female Sprague-Dawley albino rats (age: approximately 8-11 weeks; body weight: 155-217 g; source: Texas Animal Specialties, Humble, TX) were given a single dose of Tundra Max (Lot No. V.276.54.3; 28.78% chlorpyrifos and 9.22% bifenthrin; density 1.0239 g/mL; clear red solution) by oral gavage. The test substance was administered as received (first two doses only) or mixed with deionized water to produce a 10% v/v concentration. One animal was dosed at 5000 mg/kg bw in a limit test. Due to mortality in this animal, a main test was conducted using six additional animals at doses of 55 or 175 mg/kg bw and observed for 14 days.

The 5000 mg/kg animal died on day 1 after dosing. Toxic signs noted prior to death included piloerection, decreased activity, diarrhea and/or tremors. All 175 mg/kg animals died within two days of dosing. Prior to death, body tremors were noted. All 55 mg/kg animals survived and gained weight. Clinical signs of toxicity noted were piloerection, body tremors, sensitivity to sound or touch and/or polyuria. The animals recovered from these symptoms by day 3. Gross necropsy of the animals that died on test revealed wet/matted/stained muzzle fur; discolored lungs, liver and contents of the stomach; and empty stomach. No observable abnormalities were noted from any animal surviving to study termination.

Estimated female LD_{50} = 98 mg/kg bw (Based on an assumed sigma of 0.5).
Approximate 95% confidence interval is 55 to 175 mg/kg bw.

Tundra Max is in EPA Toxicity Category II.

This study is classified as acceptable. It does satisfy the guideline requirements for an acute oral study (OCSPP 870.1100; OECD 425) in the rat.

COMPLIANCE: Signed and dated GLP, Quality Assurance and Data Confidentiality statements were provided.

RESULTS AND DISCUSSION:

AOT425statpgm (Version: 1.0) Test Results and Recommendations
Acute Oral Toxicity (OECD Test Guideline 425) Statistical Program

Date/Time: Tuesday, May 11, 2010, 1:24:32 PM
Data file name: Tundra Max.dat
Last modified: 5/11/2010 1:24:31 PM

Test/Substance: Tundra Max
Test type: Main Test
Limit dose (mg/kg): 5000
Assumed LD_{50} (mg/kg): Default
Assumed sigma (mg/kg): 0.5

Recommended dose progression: 5000, 1750, 550, 175, 55, 17.5, 5.5, 1.75

DATA:

Test Seq.	Animal ID	Dose (mg/kg)	Short-term Result	Long-term Result
1	112	175	X	X
2	113	55	O	O
3	114	175	X	X
4	115	55	O	O
5	116	175	X	X
6	117	55	O	O

(X = Died, O = Survived)

Dose Recommendation: The main test is complete.

Stopping criteria met: 5 reversals in 6 tests. LR criterion.

SUMMARY OF LONG-TERM RESULTS:

Dose	O	X	Total
55	3	0	3
175	0	3	3
All Doses	3	3	6

Statistical Estimate based on long term outcomes:

Estimated LD50 = 98.11 (Based on an assumed sigma of 0.5).
Approximate 95% confidence interval is 55 to 175.

Animals were dosed as follows:

Animal Number	Sex	Dose Level (mg/kg)	Long-Term Outcome
112	F	175	D
113*	F	55	S
114*	F	175	D
115*	F	55	S
116*	F	175	D
117*	F	55	S

S = Survival, D = Death
*Test substance was diluted 10% v/v in deionized water.
Animal No. 111 dosed for limit test (5000 mg/kg) died.

Statistical Analysis: The LD_{50} value with 95% confidence interval was calculated using the AOT425 Stat Program.

A. **Mortality:** The 5000 mg/kg animal died on day 1 after dosing. All three 175 mg/kg animals died within two days of dosing.

B. **Clinical observations:** The 5000 mg/kg animal died on day 1 after dosing. Toxic signs noted prior to death included piloerection, decreased activity, diarrhea and/or tremors. All 175 mg/kg animals died within two days of dosing. Prior to death, body tremors were noted. All 55 mg/kg animals survived and gained weight. Clinical signs of toxicity noted were piloerection, body tremors, sensitivity to sound or touch and/or polyuria. The animals recovered from these symptoms by day 3.

C. **Gross necropsy:** Gross necropsy of the animals that died on test revealed wet/matted/stained muzzle fur; discolored lungs, liver and contents of the stomach; and empty stomach. No observable abnormalities were noted from any animal surviving to study termination.

D. **Reviewer's conclusions:** This reviewer agrees with the study author regarding the acute oral LD_{50}. Tundra Max is in EPA Toxicity Category II.

Reviewer: Eugenia McAndrew **Date:** May 18, 2010
Risk Manager (EPA): 13

STUDY TYPE: Acute Dermal Toxicity – Rats; OCSPP 870.1200; OECD 402

TEST MATERIAL: Tundra Max (Lot No. V.276.54.3; 28.78% chlorpyrifos and 9.22% bifenthrin; density 1.0239 g/mL; clear red solution)

CITATION: Kuhn, J. (2009) Tundra Max – Acute Dermal Toxicity Study in Rats. Study Number 12634-08. Stillmeadow, Inc., 12852 Park One Drive, Sugar Land, TX 77478. May 5, 2009. MRID 47792104.

SPONSOR: Winfield Solutions, LLC, P.O. Box 64589, St. Paul, MN 55164-0589

EXECUTIVE SUMMARY: In an acute dermal toxicity study (MRID 47792104), young adult Sprague-Dawley rats (5/sex; age: approximately 8.5 weeks; body weight: males: 272-290 g and females: 167-187 g; source: Texas Animal Specialties, Humble, TX) were dermally exposed for 24 hours on an area of approximately 10% of the total body surface area on the clipped dorsal trunk to 5050 mg/kg bw undiluted Tundra Max (Lot No. V.276.54.3; 28.78% chlorpyrifos and 9.22% bifenthrin; density 1.0239 g/mL; clear red solution) as received. The test material was applied evenly over the dose area and covered with a gauze patch and secured with non-irritating adhesive tape. The gauze and the trunk were wrapped with vet wrap and secured with non-irritating adhesive tape. The animals were observed for 14 days.

All animals survived the study. Five animals lost weight during the first week of the study but all animals gained weight by the end of the study. Clinical signs of toxicity noted were splayed legs, body tremors, polyuria, sensitivity to sound and hunched posture. Body tremors and splayed legs persisted through day 14. Very slight erythema was noted on 4/5 males and 1/5 females on day 1 with clearance by day 11. Desquamation and alopecia were noted on one male on days 11-14. No other observable abnormalities were noted from any animal at necropsy.

LD_{50} Males > 5050 mg/kg bw
LD_{50} Females > 5050 mg/kg bw
LD_{50} Combined > 5050 mg/kg bw

Tundra Max is in EPA Toxicity Category IV.

This study is classified as acceptable. It does satisfy the guideline requirements for an acute dermal study (OCSPP 870.1200; OECD 402) in the rat.

COMPLIANCE: Signed and dated GLP, Quality Assurance and Data Confidentiality statements were provided.

RESULTS and DISCUSSION:

Dose (mg/kg bw)	Mortality/Number Tested		
	Males	Females	Combined
5050	0/5	0/5	0/10

A. **Mortality:** All animals survived the study.

B. **Clinical observations:** All animals survived the study. Five animals lost weight during the first week of the study but all animals gained weight by the end of the study. Clinical signs of toxicity noted were splayed legs, body tremors, polyuria, sensitivity to sound and hunched posture. Body tremors and splayed legs persisted through day 14. Very slight erythema was noted on 4/5 males and 1/5 females on day 1 with clearance by day 11. Desquamation and alopecia were noted on one male on days 11-14.

C. **Gross necropsy:** No other observable abnormalities were noted from any animal at necropsy.

D. **Reviewer's conclusions:** This reviewer agrees with the study author regarding the acute dermal LD_{50}. Tundra Max is in EPA Toxicity Category IV.

Reviewer: Eugenia McAndrew **Date:** May 18, 2010
Risk Manager (EPA): 13

STUDY TYPE: Acute Inhalation Toxicity – Rat; OCSPP 870.1300; OECD 403

TEST MATERIAL: Tundra Max (Lot No. V.276.54.3; 28.78% chlorpyrifos and 9.22% bifenthrin; density 1.0239 g/mL; clear red solution)

CITATION: Kuhn, J. (2009) Tundra Max – Acute Inhalation Toxicity Study in Rats. Study Number 12635-08. Stillmeadow, Inc., 12852 Park One Drive, Sugar Land, TX 77478. April 7, 2009. MRID 47792105.

SPONSOR: Winfield Solutions, LLC, P.O. Box 64589, St. Paul, MN 55164-0589

EXECUTIVE SUMMARY: In an acute inhalation toxicity study (MRID 47792105), young adult Sprague-Dawley rats (5/sex/group; age: approximately 10 weeks; body weight: males: 310-356 g and females: 193-233 g; source: Texas Animal Specialties, Humble, TX) were exposed by nose-only inhalation to Tundra Max (Lot No. V.276.54.3; 28.78% chlorpyrifos and 9.22% bifenthrin; density 1.0239 g/mL; clear red solution) for 4 hours at a concentration of 2.18 mg/L. The animals were observed for 14 days. The MMAD was 3.4 µm at 1 and 3 hours, respectively, and the GSD 4.6.

One male died on day 2 and one female on day 5. All other animals survived. Clinical signs of toxicity including activity decrease, piloerection, gasping, body tremors and/or staggered gait were noted in all animals upon removal from the chamber with recovery by day 7 for the survivors. Abnormal necropsy findings occurred only in the animals that died on test and included red crust on muzzle, dark or bright red lungs, dark red or mottled liver, gas and/or green liquid in the stomach. No other observable abnormalities were noted in any animal surviving to study termination

LC_{50} Males > 2.18 mg/L
LC_{50} Females > 2.18 mg/L
LC_{50} Combined > 2.18 mg/L

Tundra Max is in EPA Toxicity Category IV.

This study is classified as acceptable. It does satisfy the guideline requirements for an acute inhalation study (OCSPP 870.1300; OECD 403) in the rat.

COMPLIANCE: Signed and dated GLP, Quality Assurance and Data Confidentiality statements were provided.

RESULTS and DISCUSSION:

Nominal Conc. (mg/L)	Gravimetric Conc. (mg/L)	MMAD µm	GSD	Mortality/Number Tested		
				Males	Females	Combined
7.37	2.18	3.4	4.6	1/5	1/5	2/10

Test Atmosphere / Chamber Description: The exposure atmosphere was generated using a 1/4 JSS air atomizer (Spraying Systems Co.), and spraying the resulting aerosol directly into the exposure chamber. Air flow was maintained at a rate of 23.4 air changes per hour and was sufficient to ensure an oxygen content of at least 19% of the exposure atmosphere. A 500 L nose-only stainless steel, dynamic flow inhalation chamber was utilized in the study. Polycarbonate tubes were inserted into individual ports where the animals were held. The test material was introduced through the opening in the top of the chamber and air flow exited the chamber to the bottom.

Gravimetric Conc. (mg/L):	**2.18**
Chamber Volume (L):	**500**
Total Airflow (L/min):	**195**
Temperature	**24°C**
Relative Humidity	**49.1-53.9%**
Time to equilibrium:	**12 minutes**

Test atmosphere concentration: During exposure, samples were collected from the breathing zone of the animals twice per hour during exposure and nominally at the end of the exposure. The samples were determined by passing a known volume of exposure air through a pre-weighed filter and dividing the amount of test material deposited on the filter by the volume of air which passed through the filter. The nominal concentration was determined by dividing the loss in weight of the test material after the exposure by the total volume of air that passed through the chamber.

Particle size determination: Particle size for each exposure concentration was determined twice using a cascade impactor, at a rate of 9.6 L/minute for 30 seconds. The mass median aerodynamic diameter and particle size distributions were calculated by a computer program using probit analysis.

A. **Mortality:** One male died on day 2 and one female on day 5. All other animals survived.

B. Clinical observations: Clinical signs of toxicity including activity decrease, piloerection, gasping, body tremors and/or staggered gait were noted in all animals upon removal from the chamber with recovery by day 7 for the survivors.

C. Gross necropsy: Abnormal necropsy findings occurred only in the animals that died on test and included red crust on muzzle, dark or bright red lungs, dark red or mottled liver, gas and/or green liquid in the stomach. No observable abnormalities were noted in any animal surviving to study termination.

D. Reviewer's conclusions: This reviewer agrees with the study author regarding the acute inhalation LC_{50}. Tundra Max is in EPA Toxicity Category IV.

Reviewer: Eugenia McAndrew **Date:** May 18, 2010
Risk Manager (EPA): 13

STUDY TYPE: Primary Eye Irritation – Rabbit; OCSPP 870.2400; OECD 405

TEST MATERIAL: Tundra Max (Lot No. V.276.54.3; 28.78% chlorpyrifos and 9.22% bifenthrin; density 1.0239 g/mL; pH 2.20; clear red solution)

CITATION: Kuhn, J. (2009) Tundra Max – Acute Eye Irritation Study in Rabbits. Study Number 12636-08. Stillmeadow, Inc., 12852 Park One Drive, Sugar Land, TX 77478. April 7, 2009. MRID 47792106.

SPONSOR: Winfield Solutions, LLC, P.O. Box 64589, St. Paul, MN 55164-0589

EXECUTIVE SUMMARY: In a primary eye irritation study (MRID 47792106), 0.1 mL of undiluted Tundra Max (Lot No. V.276.54.3; 28.78% chlorpyrifos and 9.22% bifenthrin; density 1.0239 g/mL; pH 2.20; clear red solution) was instilled as received into the conjunctival sac of the right eye of two male and one female young adult New Zealand White albino rabbits (age: approximately 3 months; source: Nichols Rabbitry Inc., Lumberton, TX). The untreated eye served as a control. The animals were observed for 72 hours and on days 4, 7, 10 and 14 and scored according to Draize.

Corneal opacity was noted on all rabbits from 24 through 72 hours after test material instillation resolving by day 7 in two eyes and by 10 in one eye. Positive conjunctival irritation was noted on 3/3 rabbits at one and 24 hours after test material instillation. No positive scores were noted on day 10 and all animals were free of irritation by day 14.

In this study, Tundra Max is classified as EPA Toxicity Category II for primary eye irritation.

This study is classified as acceptable. It does satisfy the guideline requirements for a primary eye irritation study (OCSPP 870.2400; OECD 405) in the rabbit.

COMPLIANCE: Signed and dated GLP, Quality Assurance and Data Confidentiality statements were provided.

RESULTS AND DISCUSSION:

	Number "positive"/number tested							
Observations	**Hours**				**Days**			
	1	**24**	**48**	**72**	**4**	**7**	**10**	**14**
Corneal Opacity	0/3	3/3	3/3	3/3	2/3	1/3	0/3	0/3
Iritis	0/3	0/3	0/3	0/3	0/3	0/3	0/3	0/3
*Conjunctivae:								
*Redness	1/3	2/3	2/3	1/3	1/3	0/3	0/3	0/3
*Chemosis	3/3	3/3	2/3	1/3	1/3	0/3	0/3	0/3
*Discharge	3/3	3/3	2/3	0/3	0/3	0/3	0/3	0/3

* Score of 2 or more required to be considered "positive"
** Discharge is not a positive effect according to the grading scale

A. **Observations:** Corneal opacity was noted on all rabbits from 24 through 72 hours after test material instillation resolving by day 7 in two eyes and by 10 in one eye. Positive conjunctival irritation was noted on 3/3 rabbits at one and 24 hours after test material instillation. No positive scores were noted on day 10 and all animals were free of irritation by day 14.

B. **Results:** Tundra Max was moderately irritating by the Kay and Calandra scoring system. The highest maximum mean total score was 36.7, recorded 24 hours after treatment.

C. **Reviewer's conclusions:** This reviewer agrees with the study author that the test material was moderately irritating. Tundra Max is classified as EPA Toxicity Category II for primary eye irritation.

Reviewer: Eugenia McAndrew **Date:** May 18, 2010
Risk Manager (EPA): 13

STUDY TYPE: Primary Dermal Irritation – Rabbit; OCSPP 870.2500; OECD 404

TEST MATERIAL: Tundra Max (Lot No. V.276.54.3; 28.78% chlorpyrifos and 9.22% bifenthrin; density 1.0239 g/mL; clear red solution)

CITATION: Kuhn, J. (2009) Tundra Max – Acute Dermal Irritation Study in Rabbits. Study Number 12637-08. Stillmeadow, Inc., 12852 Park One Drive, Sugar Land, TX 77478. March 31, 2009. MRID 47792107.

SPONSOR: Winfield Solutions, LLC, P.O. Box 64589, St. Paul, MN 55164-0589

EXECUTIVE SUMMARY: In a primary dermal irritation study (MRID 47792107), two male and one female young adult New Zealand White rabbits (age: 14 weeks; source: Nichols Rabbitry Inc., Lumberton, TX) were dermally exposed to 0.5 mL of undiluted Tundra Max (Lot No. V.276.54.3; 28.78% chlorpyrifos and 9.22% bifenthrin; density 1.0239 g/mL; clear red solution) for 4 hours on an area of the clipped dorsal skin (8 x 8 cm) that was covered with a 2.5 x 2.5 cm gauze patch. The patch and trunk were wrapped with semi-permeable dressing and secured with strips of tape. The animals were observed and irritation was scored at 1, 24, 48, and 72 hours after patch removal.

Very slight erythema was noted at 3/3 test sites at 48 and 72 hours. All sites were free of irritation by day 7.

In this study, the formulation was not irritating. Tundra Max is classified as EPA Toxicity Category IV for primary dermal irritation.

This study is classified as acceptable. It does satisfy the guideline requirements for a primary dermal irritation study (OCSPP 870.2500; OECD 404) in the rabbit.

COMPLIANCE: Signed and dated GLP, Quality Assurance and Data Confidentiality statements were provided.

RESULTS AND DISCUSSION:

Erythema/Edema

Animal Number/Sex	Hours After Patch Removal				Days
	1	24	48	72	7
3626/M	0/0	0/0	1/0	1/0	0/0
3648/M	0/0	0/0	1/0	1/0	0/0
3647/F	0/0	0/0	1/0	1/0	0/0

A. **Observations:** Very slight erythema was noted at 3/3 test sites at 48 and 72 hours. All sites were free of irritation by day 7.

B. **Results:** Tundra Max was slightly irritating. The Primary Irritation Index (PII) is 0.5.

C. **Reviewer's conclusions:** This reviewer agrees with the study author that the test material was slightly irritating. Tundra Max is classified as EPA Toxicity Category IV for primary dermal irritation.

Reviewer: Eugenia McAndrew **Date:** May 18, 2010
Risk Manager (EPA): 13

STUDY TYPE: Dermal Sensitization – guinea pig; OCSPP 870.2600; OECD 406

TEST MATERIAL: Tundra Max (Lot No. V.276.54.3; 28.78% chlorpyrifos and 9.22% bifenthrin; density 1.0239 g/mL; clear red solution)

CITATION: Kuhn, J. (2009) Tundra Max – Skin Sensitization Study in Guinea Pigs. Study Number 12638-08. Stillmeadow, Inc., 12852 Park One Drive, Sugar Land, TX 77478. April 28, 2009. MRID 47792108.

SPONSOR: Winfield Solutions, LLC, P.O. Box 64589, St. Paul, MN 55164-0589

EXECUTIVE SUMMARY: In a dermal sensitization study (MRID 47792108) with Tundra Max (Lot No. V.276.54.3; 28.78% chlorpyrifos and 9.22% bifenthrin; density 1.0239 g/mL; clear red solution), 15 male and 15 female young adult Hartley albino guinea pigs (age: approximately 7 weeks; body weight: males: 364-435 g; females: 345-425 g; source: Charles River Laboratories, Wilmington, MA) were tested using the Buehler Method. The test animals were induced with 0.4 mL undiluted test material applied beneath a surgical gauze patch to the clipped back at the left front quadrant for six hours. The procedure was repeated once each week for three consecutive weeks. After a two week rest period, the animals were challenged with 0.4 mL undiluted test material at a naive site. The naive control animals were treated with 0.4 mL undiluted test material under occlusion at challenge. Reactions were scored 24 and 48 hours after test material applications.

After three consecutive weekly inductions, no dermal reactions were noted from any test or anive control animal after challenge.

Based on the results of this study, Tundra Max was not a dermal sensitizer.

This study is classified as acceptable. It does satisfy the guideline requirements for a dermal sensitization study (OCSPP 870.2600; OECD 406) in the guinea pigs.

COMPLIANCE: Signed and dated GLP, Quality Assurance and Data Confidentiality statements were provided.

PROCEDURE:

A. **Induction**: The animals were induced and challenged according to the Buehler method. The backs of the animals were clipped one day prior to each treatment. For the induction, the 20 test animals were induced with 0.4 mL undiluted test material applied beneath a 4 ply, 2.5 x 2.5 cm surgical gauze patch to the clipped back at the left front quadrant and secured with non-irritating adhesive tape. A strip of clear polyethylene film was placed over the patch and securely taped. Each animal was then placed in a restrainer. After approximately six hours, the animals were removed from the restrainer and the coverings were removed. The induction was performed once each week for three weeks. Reactions were scored 24 and 48 hours after the first induction and 24 hours after the second and third inductions.

B. **Challenge**: After a two week rest period, the animals were challenged. The backs of the animals were clipped one day prior to challenge. The test animals were challenged with 0.4 mL undiluted test material at a naive site (right rear quadrant) and secured with non-irritating adhesive tape. After six hours of exposure, reactions were scored 24 and 48 hours after exposure.

C. **Naive control:** The naive control animals were not treated during the induction phase. The backs of the animals were clipped one day prior to challenge. The naive control animals were challenged with 0.4 mL undiluted test material. After six hour of exposure, reactions were scored 24 and 48 hours after exposure.

RESULTS AND DISCUSSION:

A. **Reactions and durations**: No dermal irritation was noted on any test or naive control animal after inductions or challenge. The test material was not a dermal sensitizer.

B. **Positive control**: The positive control study # 11950-08 included in the study report was conducted eight months before the main study. The study author was able to provide a positive control (alpha-hexylcinnamaldehyde) study # 12455-08 which was conducted within six months of the current study; the results were appropriate.

C. **Reviewer's conclusion**: This reviewer agrees with the study author that the test material was not a dermal sensitizer.

1. **DP BARCODE:** DP370218
2. **PC CODES:** 059101, 128825
3. **CURRENT DATE:** May 18, 2010
4. **TEST MATERIAL:** Tundra Max (Lot No. V.276.54.3; 28.78% chlorpyrifos and 9.22% bifenthrin; density 1.0239 g/mL; clear red solution)

Study/Species/Lab Study # / Date	MRID	Results	Tox. Cat.	Core Grade
Acute oral toxicity/rat Stillmeadow, Inc. 12633-08/May 1, 2009	47792103	LD_{50} = 98 mg/kg bw females	II	A
Acute dermal toxicity/rat Stillmeadow, Inc. 12634-08/May 5, 2009	47792104	LD_{50} > 5050 mg/kg bw males, females combined	IV	A
Acute inhalation toxicity/rat Stillmeadow, Inc. 12635-08/April 7, 2009	47792105	LC_{50} > 2.18 mg/L males, females combined	IV	A
Primary eye irritation/rabbit Stillmeadow, Inc. 12636-08/April 7, 2009	47792106	Corneal opacity and conjunctivitis resolving by day 10	II	A
Primary dermal irritation/rabbit Stillmeadow, Inc. 12637-08/March 31, 2009	47792107	Slightly irritating	IV	A
Dermal sensitization/Guinea pig Stillmeadow, Inc. 12638-08/April 28, 2009	47792108	Not sensitizing	-	A

Core Grade Key: A = Acceptable, S = Supplementary, U = Unacceptable, W = Waived